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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,872	12/18/2006	Kohji Nishida	BJS-5202-2	3907

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EXAMINER	
SGAGIAS, MAGDALENE K	
ART UNIT	PAPER NUMBER
1632	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,872	NISHIDA ET AL.	
	Examiner	Art Unit	
	MAGDALENE K. SGAGIAS	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-70* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-70 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-8, drawn to an adipose tissue derived cell for use as a feeder cell.

Group II, claim(s) 9-28, drawn to a method for preparing a transplant for regenerating an organ, tissue or cell of a subject, comprising the steps of: A) providing part of a desired organ, tissue or cell or a stem cell capable of differentiation there into; and B) culturing the part or the stem cell on a feeder cell comprising an adipose tissue derived cell.

Group III, claim(s) 29-35, drawn to a system for regenerating an organ, tissue or cell of a subject, comprising: A) a vessel; and B) a feeder cell comprising an adipose tissue derived cell.

Group IV, claim(s) 36, drawn to a method for regenerating an organ, tissue or cell of a subject, comprising the steps of: A) providing part of a desired organ, tissue or cell or a stem cell capable of differentiation there into; B) culturing the part or the stem cell on a feeder cell comprising an adipose tissue derived cell; and C) transplanting the cultured part or stem cell to a site to be treated of the subject.

Group V, claim(s) 37, drawn to a method for regenerating an organ, tissue or cell of a subject, comprising the step of: A) transplanting part of a desired organ, tissue or cell or a stem cell capable of differentiation there into and a feeder cell comprising an adipose tissue derived cell to a site to be treated of the subject.

Group VI, claim(s) 38, drawn to a pharmaceutical composition for regenerating an organ, tissue or cell of a subject, comprising: A) part of a desired organ, tissue or cell or a stem cell capable of differentiation there into and a feeder cell comprising an adipose tissue derived cell.

Group VII, claim(s) 39-41, drawn to use of an adipose tissue derived cell as a feeder cell.

Group VIII, claim(s) 42, drawn to a primary cultured human fibroblasts for use as a feeder cell.

Group IX, claim(s) 43, drawn to a method for preparing a transplant for regenerating an organ, tissue or cell of a subject, comprising the steps of: A) providing part of a desired organ, tissue or cell or a stem cell capable of differentiation there into; and B) culturing the part or the stem cell on a feeder cell comprising a primary cultured human fibroblasts.

Group X, claim(s) 44, drawn to a system for regenerating an organ, tissue or cell of a subject, comprising: A) a vessel; and B) a feeder cell comprising a primary cultured human fibroblasts.

Group XI, claim(s) 45, drawn to a method for regenerating an organ, tissue or cell of a subject, comprising the steps of: **A)** providing part of a desired organ, tissue or cell or a stem cell capable of differentiation there into; **B)** culturing the part or the stem cell on a feeder cell comprising a primary cultured human fibroblasts; and **C)** transplanting the cultured part or stem cell to a site to be treated of the subject.

Group XII, claim(s) 46, drawn to a method for regenerating an organ, tissue or cell of a subject, comprising the step of**: A)** transplanting part of a desired organ, tissue or cell or a stem cell capable of differentiation there into and a feeder cell comprising a primary cultured human fibroblasts to a site to be treated of the subject.

Group XIII, claim(s) 47, drawn to a pharmaceutical composition for regenerating an organ, tissue or cell of a subject, comprising: A) part of a desired organ, tissue or cell or a stem cell capable of differentiation there into and a feeder cell comprising a primary cultured human fibroblasts.

Group XIV, claim(s) 48-50, drawn to use of a primary cultured human fibroblasts as a feeder cell.

Group XV, claim(s) 51-64, drawn to a graft for regenerating an epithelial tissue which contains a stem cell or a cell derived from the stem cell.

Group XVI, claim(s) 65-70, drawn to use for preparing a pharmaceutical composition as a graft for regenerating an epithelial tissue, the graft containing a stem cell or a cell derived from the stem cell.

The inventions listed as Groups I-XVI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking the inventions of groups I-XVI is providing an adipose tissue derived cell for use as a feeder cell. Wilkison et al (WO 01/62901) teaches a adipose derived

cells for use as a feeder cell (abstract). Therefore, the instant technical feature of groups I-XVI does not make a contribution over the prior art. Furthermore, the claimed methods of groups II, IV-V, VII, XI-XII, XIV and XVI have distinct steps, produce different products and/or results, which are not coextensive.

Election of organ, tissue or cell type.

1. If applicants elect a group including claims 11, 53, 55, 67, 69 and their dependant claims a further election is required in said claims. Applicants is required to elect either only one organ, or only one tissue or only one cell type for prosecution. This restriction is because each organ, tissue, or cell type requires distinct methods of preparing a transplant for regeneration. Applicant is required to elect only one organ or only tissue or only one cell, even though this is not an election of species it is a restriction requirement.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement ay be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim

will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAGDALENE K. SGAGIAS whose telephone number is (571)272-3305. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paras Peter can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Anne-Marie Falk/
Anne-Marie Falk, Ph.D.
Primary Examiner, Art Unit 1632